

10/588430

IAP11 Rec'd PCT/PTO 04 AUG 2006¹

APPLICATION OF

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FOR IMPROVEMENTS IN

**METHOD AND SYSTEM OF PROVIDING SEALED BAGS OF FLUID
AT THE CLEAN SIDE OF A LABORATORY FACILITY**

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Our Docket No. 364106/0379

Express Mail Label No. EV 085825099 US

**METHOD AND SYSTEM OF PROVIDING SEALED BAGS OF FLUID
AT THE CLEAN SIDE OF A LABORATORY FACILITY**

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application is a Continuation-In-Part of U.S. Patent Application Serial Number 10/274,619, filed on October 21, 2002, and entitled Fluid Deliver System, currently pending, which claims the benefit of U.S. Provisional Patent Application Serial Number 60/346,218, filed on October 19, 2001, the contents of both applications being hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[002] The present invention relates generally to fluid delivery systems and in particular to a fluid delivery system and method for caging or storage systems for animals.

2. Description of Related Art

[003] A large number of laboratory animals are used every year in experimental research. These animals range in size from mice to non-human primates. To conduct valid and reliable experiments, researchers must be assured that their animals are protected from pathogens and microbial contaminants that will affect test results and conclusions. Proper housing and management of animal facilities are essential to animal well-being, to the quality of research data and teaching or testing programs in which animals are used, and to the health and safety of personnel.

[004] Ordinarily, animals should have access to potable, uncontaminated drinking water or other needed nutrient containing fluids according to their particular requirements. Water quality and the definition of potable water can vary with locality. Periodic monitoring for pH, hardness, and microbial or chemical contamination might be necessary to ensure that

water quality is acceptable, particularly for use in studies in which normal components of water in a given locality can influence the results obtained. Water can be treated or purified to minimize or eliminate contamination when protocols require highly purified water. The selection of water treatments should be carefully considered because many forms of water treatment have the potential to cause physiologic alterations, changes in microflora, or effects on experimental results. For example, chlorination of the water supply can be useful for some species but toxic to others.

[005] Because the conditions of housing and husbandry affect animal and occupational health and safety as well as data variability, and effect an animal's well-being, the present invention relates to providing a non-contaminated, replaceable, disposable source of fluid for laboratory animals in a cage level barrier-type cage or integrated cage and rack system to permit optimum environmental conditions and animal comfort.

[006] Animal suppliers around the world have experienced an unprecedented demand for defined pathogen-free animals, and are now committed to the production and accessibility of such animals to researchers. Likewise, laboratory animal cage manufacturers have developed many caging systems that provide techniques and equipment to insure a pathogen free environment. For example, ventilated cage and rack systems are well known in the art. One such ventilated cage and rack system is disclosed in U.S. Patent No. 4,989,545, the contents of which are incorporated herein by reference, assigned to Lab Products, Inc., in which an open rack system including a plurality of shelves, each formed as an air plenum, is provided. A ventilation system is connected to the rack system for ventilating each cage in the rack, and the animals therein, thereby eliminating the need for a cage that may be easily contaminated with pathogens, allergens, unwanted pheromones, or other hazardous fumes. It is known to house rats, for example, for study in such a ventilated cage and rack system.

[007] The increasing need for improvement and technological advancement for efficiently, safely housing and maintaining laboratory animals arises mainly from contemporary interests in creating a pathogen-free laboratory animal environment and through the use of immuno-compromised, immuno-deficient, transgenic and induced mutant ("knockout") animals. Transgenic technologies, which are rapidly expanding, provide most of the animal populations for modeling molecular biology applications. Transgenic animals account for the continuous success of modeling mice and rats for human diseases, models of disease treatment and prevention and by advances in knowledge concerning developmental genetics. Also, the development of new immuno-deficient models has seen tremendous advances in recent years due to the creation of gene-targeted models using knockout technology. Thus, the desire for an uncontaminated cage environment and the increasing use of immuno-compromised animals (i.e., SCID mice) has greatly increased the need for pathogen free sources of food and water. One of the chief means through which pathogens can be introduced into an otherwise isolated animal caging environment is through the contaminated food or water sources provided to the animal(s).

[008] Accordingly, the need exists to improve and better maintain the health of research animals through improving both specialized caging equipment and the water delivery apparatus for a given cage. Related caging system technologies for water or fluid delivery have certain deficiencies such as risks of contamination, bio-containment requirements, DNA hazardous issues, gene transfer technologies disease induction, allergen exposure in the workplace and animal welfare issues.

[009] Presently, laboratories or other facilities provide fluid to their animals in bottles or other containers that must be removed from the cage, disassembled, cleaned, sterilized, reassembled, and placed back in the cage. Additionally, a large quantity of fluid bottles or

containers must be stored by the labs based on the possible future needs of the lab, and/or differing requirements based on the types of animals studied. This massive storage, cleaning and sterilization effort, typically performed on a weekly basis, requires large amounts of time, space and human resources to perform these repetitive, and often tedious tasks.

[0010] Further, glass bottles (and the handling thereof) can be dangerous and also relatively costly. Bottle washing machines, bottle fillers, wasted water, hot water, wire baskets to hold bottles, sipper tubes, rubber stoppers, the ergonomic concerns of removing stoppers, screw caps insertion of sipper tubes are all problems inherent to the use of water bottles to provide water to animals.

[0011] Although automatic watering systems are available the cost per cage is too costly for many institutions. Stainless steel valves and manifolds need constant purging of slime and buildup of mineral deposits.

[0012] The human factors of handling wire baskets while loading and unloading bottles has led to industry wide back injuries, carpal wrist injury, and eye injury from broken glass and other human factor ergonomic risks. By some estimates, the cost of injury related costs to industry and the lost productivity in the workplace amount to millions of dollars annually.

[0013] In addition, the use of water bottles typically leads to large energy costs because the cleaning of the water bottles typically requires hot water heated to approximately 180 degrees F and the washing of all of the components of the water bottles and caps with dangerous chemicals. As such, a need exists for an improved system for delivering fluid to laboratory animals living in cage level barrier-type rack and cage systems.

SUMMARY OF THE INVENTION

[0014] The present invention satisfies this and other needs. Briefly stated, in accordance with an embodiment of the invention, a fluid delivery system for delivering a fluid

to an animal caging system for housing an animal is described. The fluid delivery system may comprise a fluid delivery valve assembly adapted to be coupled to a fluid bag holding a fluid. By advantageously using sanitized fluid bags, that may be disposable, the invention may minimize the need for the use of fluid bottles that typically must be removed from cages, cleaned, and sanitized on a frequent basis.

[0015] The delivery system may be utilized in a single cage or in multiples cages integrated into ventilated cage and rack systems known in the art. An embodiment of the invention described herein provides for a fluid delivery system for delivering a fluid from a fluid bag to an animal caging system for housing an animal and may comprise a fluid delivery valve assembly, wherein the fluid delivery valve assembly is adapted to be coupled to the fluid bag to facilitate the providing of the fluid to an animal in the caging system. The fluid delivery valve assembly may further comprise an upper member having a piercing member and a connecting member, the upper member having a fluid channel defined therethrough, a base having a flange member and a base fluid channel defined therethrough, wherein the base is designed to be matingly coupled to the upper member. The fluid delivery valve assembly may further comprise a spring element disposed within the base fluid channel and a stem member disposed in part within the base fluid channel, wherein a portion of the spring element abuts the stem member to apply a biasing force.

[0016] Another embodiment of the invention may provide for a method for delivering fluid to one or more animal cages comprising providing sealed sanitized bags of fluid for use in an animal cage or caging system. The method may further comprise providing bag material to be used in the formation of fluid bags.

[0017] Another embodiment is directed to a method for facilitating the delivery of water to a plurality of cage level barrier-type cages, for housing animals for an animal study.

The method comprises providing a plurality of cage level barrier-type cages for an animal study at a laboratory facility site, and disposing a bag forming apparatus at a clean side of a laboratory washroom at the laboratory facility site. The bag forming apparatus is capable of providing sealed bags of water for use in the cage level barrier-type cages. In addition, the method can further comprise providing bag material to the laboratory facility site.

[0018] Another embodiment of the invention involves a method for facilitating the delivery of water to a plurality of cage level barrier-type cages disposed at a laboratory facility site, for housing animals for an animal study,. The method comprises disposing a bag forming apparatus at a clean side of a laboratory washroom at the laboratory facility site; wherein the bag forming apparatus is capable of providing sealed bags of water for use in the cage level barrier-type cages.

[0019] Another embodiment of the invention is directed to a system for facilitating the delivery of water to a plurality of cage level barrier-type cages disposed at a laboratory facility site, for housing animals for an animal study. The system comprises a bag forming apparatus designed and configured for placement at a clean side of a laboratory washroom at the laboratory facility site, wherein the bag forming apparatus is capable of providing sealed bags of water for use in the cage level barrier-type cages.

[0020] Still other objects and advantages of the invention will in part be obvious and will in part be apparent from the specification. Other features and advantages of this invention will become apparent in the following detailed description of exemplary embodiments of this invention with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] In the drawing figures, which are merely illustrative, and wherein like reference characters denote similar elements throughout the several views:

[0022] FIG. 1 is an exploded perspective view of a fluid delivery system incorporated into an animal cage assembly;

[0023] FIG. 2 is an exploded perspective view of a fluid delivery system and diet delivery system in accordance with the present invention;

[0024] FIG. 3 is an exploded perspective view of an embodiment of a fluid delivery valve assembly in accordance with the present invention;

[0025] FIG. 4 is a side view of the fluid delivery valve assembly of FIG. 3;

[0026] FIG. 5 is a side cutaway view of the upper member of the fluid delivery valve assembly of FIG. 3;

[0027] FIG. 6 is a perspective view of trigger assembly of a fluid delivery valve assembly in accordance with the present invention;

[0028] FIG. 7 is a top plain view of cup element in accordance with the present invention;

[0029] FIG. 8 is a perspective view of the cup element in accordance with the present invention;

[0030] FIG. 9 is a cutaway view of cup element in accordance with the present invention;

[0031] FIG. 10 is a perspective view of a diet delivery system;

[0032] FIG. 11 is a top plan view of diet delivery system incorporating a fluid delivery system in accordance with the present invention;

[0033] FIG. 12 is a front cutaway view of diet delivery system;

[0034] FIG. 13 is a bottom view of a fluid bag in accordance with the present invention;

[0035] FIG. 14 is a perspective view of a fluid bag and a fluid diet component with a fluid delivery system in accordance with the present invention;

[0036] FIG. 15 is a cutaway view of a fluid bag in accordance with the present invention;

[0037] FIG. 16 is a side perspective view of an upper member of a fluid delivery valve assembly including a support in accordance with the present invention;

[0038] FIG. 17 is a plain side view of a double-sided rack system incorporating an animal cage;

[0039] FIG. 18 is an exploded perspective view of an embodiment of a fluid delivery valve assembly in accordance with the present invention;

[0040] FIG. 19 is a side cutaway view of the fluid delivery valve assembly of FIG. 18;

[0041] FIG. 20 is a perspective view of the stem of the fluid delivery valve assembly of FIG. 18;

[0042] FIG. 21 is a side cutaway view of the fluid delivery valve assembly of FIG. 18, showing the stem in the sealed position;

[0043] FIG. 22 is a side cutaway view of the fluid delivery valve assembly of FIG. 18, showing the stem in the opened position;

[0044] FIG. 23 is a side cutaway view of the fluid delivery valve assembly of FIG. 18, showing the extension portion protecting the stem;

[0045] FIG. 24 is a side cutaway view of an upper member of a fluid delivery valve assembly including a wrapper in accordance with the present invention;

[0046] FIG. 25 is a side cutaway view of an upper member of a fluid delivery valve assembly including a disposable cap in accordance with the present invention;

[0047] FIG. 26 is a fluid bag filling and sealing device in accordance with the present invention;

[0048] FIG. 27 is a view of a fluid bag preparation room in accordance with the present invention;

[0049] FIG. 28 is another view of a fluid bag preparation room in accordance with the present invention;

[0050] FIG. 29 is another view of a fluid bag preparation room in accordance with the present invention;

[0051] FIG. 30 is a schematic diagram of equipment used in certain embodiments;

[0052] FIG. 31 is a schematic plan view of a laboratory facility illustrating a flow pattern and placement of a bag forming and filling apparatus;

[0053] FIG. 32 is a schematic plan view of a laboratory facility illustrating another flow pattern and placement of a bag forming and filling apparatus;

[0054] FIG. 33 is flow diagram illustrating an exemplary process in accordance with certain embodiments; and

[0055] FIG 34 is another flow diagram illustrating another exemplary process in accordance with certain embodiments.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0056] Reference is made to FIGS. 1 and 2, wherein an animal cage assembly 90, which incorporates fluid delivery valve assembly 1, is shown. Cage assembly 90 incorporates a filter retainer 91, a filter frame 92, a filter top lock 93, a chew shield 94, a plurality of snap rivets 95, a fluid bag 60 containing fluid 70, a fluid delivery valve assembly 1, a diet delivery system 96 providing support member 50, a chow receptacle 111, a fluid bag receptacle 110, and a cage body 98. Cage body 98 comprises a box-like animal cage with a combination diet

delivery system 96 capable of providing both food and fluid to animals within cage assembly 90. A filter 99 is also generally provided with cage assembly 90 sandwiched between filter retainer 91 and filter frame 92. Cage body 98 is formed with integral side walls 100, a bottom wall or floor 101 and an open top end. The open top of cage body 98 is bordered by peripheral lip 102, which extends continuously there around. Cage body 98 may also include a plurality of corner stacking tabs 103 for facilitating stacking and nesting of a plurality of cage bodies 98.

[0057] Reference is made to FIGS. 3-5 wherein fluid delivery valve assembly 1 is depicted. Fluid delivery valve assembly 1 includes an upper member 10, a spring element 20, a trigger assembly 30, and a cup element 40 for use in animal cage 90. Water delivery system 1 is held in place in animal cage 90 by support element 50. Support element 50 extends from diet delivery system 96 and forms a floor for fluid bag receptacle 110. Alternatively, water delivery system 1 may be molded into diet delivery system 96.

[0058] As shown in FIGS. 4 and 5, upper member 10 includes piercing member 11, core member 12 and flange member 13. Upper member 10 also defines fluid channel 14. Arrow "A" defines the flow of fluid through fluid delivery valve assembly 1 to trigger assembly 30 where fluid flow can be actuated by an animal in animal cage 90. Piercing member 11 has a beveled tip 15 at its upper end, the upper edge of which presents a sharp piercing edge 16 that can come in contact and pierce fluid bag 60, releasing fluid 70 in fluid bag 60 through fluid channel 14. Flange member 13 extends from core member 12. In a preferred embodiment, flange member 13 is circular in dimension. However, it will be readily understood by one of ordinary skill in the art that flange member 13 may be any shape desired, provided however, that at least a portion of flange member 13 is wider in diameter than fluid channel 14 of core member 12. As shown in FIG. 3, spring element 20 may be a tightly wound coiled member which rests atop tip 35 of upper end 33 of stem 31 and enters upper member 10

through fluid channel 14. As shown in FIG. 5, fluid channel 14 is dimensioned such that its upper extent within piercing member 11 is narrowed at position 17 such that it prevents spring element 20 from exiting fluid channel 14 through piercing member 11.

[0059] Reference is made to FIG. 6, wherein trigger assembly 30 is depicted. Trigger assembly 30 includes a stem 31, inserted through sealing member 32. Stem 31 having an upper end 33 and a lower end 36. Lower end 36 of stem 31 is substantially flat. Upper end 33 of stem 31 is generally conical in shape, although other shapes may be used. Sealing member 32 fits tightly around stem 31 thereby allowing limited movement around stem 31. Sealing member 32 is dimensioned such that the base of the conical portion of upper end 33 rests on it. Sealing member 32 is formed of a resilient material, such as rubber, silicone rubber, or any other pliant malleable material. In a preferred embodiment, sealing member 32 is made of a material that is not deleterious to mammals.

[0060] Cup element 40 is depicted in FIGS. 7-9. Cup element 40 has a base 43, an inner surface 41, and an outer surface 42. Base 43 also defines actuation channel 400. Lower end 36 of stem 31 of trigger assembly 30 extends through actuation channel 400 towards the interior of animal cage 90. Fluid channel 14 extends from piercing edge 16 through piercing member 11, core member 12 and spring element 20. Fluid channel 14 terminates at the bottom wall of cup element 40. Trigger assembly 30 extends through actuation channel 400. Cup element 40 has friction fit with core member 12 of upper member 10 directly below flange member 13.

[0061] Diet delivery system 96, which houses fluid bag receptacle 110 and chow receptacle 111 is shown in FIGS. 10-12. As shown in FIG. 11, fluid bag receptacle 110 holds fluid bag 60 containing fluid 70. Fluid delivery valve assembly 1 is held securely in receptacle base 112 of fluid bag receptacle 110 by the interconnection between flange members 13a, 13b,

13c and 13d and locking members 51a, 51b, 51c and 51d. Piercing edge 16 of fluid delivery valve assembly 1 punctures fluid bag 60. As shown in FIGS. 11 and 12, chow receptacle 111 of diet delivery system 96 holds wire food holder element 116. A further embodiment of the present invention is shown in FIGS. 10 and 12, wherein fluid bag receptacle 110 may be molded 110' in order to facilitate the emptying of fluid 70 contained in fluid bag 60 by fluid delivery valve assembly 1 and to prevent the animal from gaining purchase on the fluid bag receptacle. In an alternate embodiment, fluid bag 60 is tapered or dimensioned so as to facilitate the emptying of fluid bag 60 by fluid delivery valve assembly 1. Fluid bag 60 may be made replaceable or disposable and thus may be manufactured singly in any quantity according to the needs of a user.

[0062] Fluid delivery valve assembly 1 may be used to deliver the contents of fluid bag 60 to an animal in cage assembly 90. Fluid 70 in fluid bag 60 may include water, distilled water, water supplemented with various vitamins, minerals, medications such as antibiotics or anti-fungal agents, and/or other nutrients, or any fluid which is ingestible by a caged animal. Fluid 70 in fluid bag 60 is delivered to an animal in cage assembly 90 in a sterilized or sanitized condition so as to protect any animals in cage assembly 90 from contagion. Fluid bag 60 may be formed in any desirable shape or volume. In a preferred embodiment, fluid bag 60 is formed to fit fluid bag receptacle 110.

[0063] Also, it should be clear that fluid bag 60 does not have to consist of a flexible material but that part thereof may be made of a rigid material. In an embodiment of the present invention, fluid bag 60 would consist of one or more layers, which would tear upon insertion of piercing member 11. Alternatively, flexible, stretchable, resilient plastic stickers 501 may be provided which can be adhered to the bag to prevent tearing thereof and to form a seal about the inserted piercing member 11. In addition, as depicted in FIGS. 13-15, fluid bag

60 could be made of a thinner plastic or inverted in the region where piercing edge 16 will penetrate fluid bag 60, thereby allowing the end user to readily identify where fluid bag 60 should be punctured and helping fluid bag 60 nest within fluid bag receptacle 110. In a further embodiment of the present invention, fluid bag 60 could be made of a resilient plastic or polymer material such that when piercing edge 16 penetrates fluid bag 60 at location 88, fluid bag 60 adheres to piercing member 16 so as to stop fluid 70 from leaking out of fluid bag 60. Fluid bag 60 may be constructed out of any material which is capable of being punctured by piercing member 16 and which is capable of holding fluid in a sterilized condition. In an embodiment of the invention, fluid bag 60 is plastic or any other flexible material capable of containing a fluid to be delivered to one or more laboratory animals. In certain embodiments, fluid bag 60 may be formed of nylon or polyethylene film in a single layer or multilayer design. With use of a multilayer film, different layers can each have different properties. For example, the inner layers could provide sealing properties, while the outer layers provide resistance to tearing, or vice versa. In a further embodiment of the present invention, fluid delivery valve assembly 1, upper member 10, fluid bag 60 and the contents thereof, fluid 70, are capable of being sterilized by one or more of an assortment of different means including but not being limited to: ultraviolet light, irradiation, chemical treatment, reverse osmosis, gas sterilization, steam sterilization, filtration, autoclave, and/or distillation. Each of the elements of the current invention, fluid delivery valve assembly 1, fluid bag 60 and fluid 70, can be sterilized or sanitized alone or in combination with each other. Fluid 70 of fluid bag 60 may be sterilized either before or after fluid bag 60 is sealed.

[0064] In one embodiment providing a method of sterilization for the contents of fluid bag 60, a chemical compound capable of sterilizing the fluid 70, and known in the art, is put inside fluid bag 60 with fluid 70 prior to fluid bag 60 being sealed. Thereafter the compound

sterilizes fluid 70 such that it can be delivered to an animal and consumed by that animal without harm. Other methods of sterilization are discussed below.

[0065] In an embodiment of the invention, leak preventing member 501 is affixed or formed to upper member 10 and prevents a loss of fluid 70 from fluid bag 60 after puncture by piercing member 11.

[0066] As shown in FIG. 14, piercing member 11 may be rigidly fixed to support element 50 of fluid bag receptacle 110 (see FIGS. 1 and 4), in particular in the support for the bag having its point directed upwards so that piercing member 11 is automatically inserted into fluid bag 60 at location 88 when placing fluid bag 60 onto support element 50 or into fluid bag receptacle 110'.

[0067] In one embodiment of the present invention, fluid bag 60 is placed in fluid bag receptacle 110 of animal cage 90. Fluid bag receptacle 110 has a base 112, an inner surface 114 and an outer surface 115. Receptacle base 112 also defines actuation channel 400. When fluid delivery valve assembly 1 is used in conjunction with animal cage 90, stem 31 of trigger assembly 30 extends through cup 40 towards the interior of animal cage 90. In another embodiment, that portion of receptacle base 112 which encircles actuation channel 400 may include one or more locking members 51.

[0068] As shown in FIG. 16, in an alternate embodiment, support member 50 may have four (or some other number of) locking members 51a, 51b, 51c and 51d formed thereon which may be used to secure flange members 13a, 13b, 13c and 13d to support member 50. It will be readily understood by one of ordinary skill in the art that flange members 13a, 13b, 13c and 13d may vary in shape, provided however, that flange members 13a, 13b, 13c and 13d are secured in fluid receptacle base 112 or onto support member 50 by its locking members 51a, 51b, 51c and 51d. In FIG. 16, locking members 51a, 51b, 51c and 51d are shaped like fingers

and flange member 13 is divided into four equal pieces, shown as flange members 13a, 13b (not shown), 13c and 13d.

[0069] Referring now to FIG. 17, an animal isolation and caging rack system 600 of the invention includes an open rack 615 having a left side wall 625 and a right side wall 630, a plurality of rack coupling stations 616, a top 635, and a bottom 640. A plurality of posts 645 are disposed in parallel between top 635 and bottom 640. Vertical posts 645 are preferably narrow and may comprise walls extending substantially from the front of rack 615 to the rear of rack 615, or may each comprise two vertical members, one at or near the front of rack 615 and the other at or near the rear of rack 615. Animal isolation and caging rack system 600 also includes a plurality of air supply plena 610 and air exhaust plena 620 alternately disposed in parallel between left side wall 625 and right side wall 630 in rack 615.

[0070] The above discussed fluid delivery valve assembly 1, while facilitating the providing of fluid to animals, was found to have some deficiencies when used in conjunction with certain rack and cage system configurations. For example, with reference back to FIG. 3, when the stem 31 of the trigger assembly 30 is actuated by an animal, under certain circumstances, the stem may remain stuck in the open position even after the animal discontinues actuating the stem 31. If the stem remains stuck in the open position, fluid may continue to leak into the cage and cage bedding, with the result being a waste of fluid, and the potential for the animal to become hypothermic, or otherwise adversely affected.

[0071] One reason for the occurrence of this problem in certain circumstances may be that due to the specific arrangement of the stem 31, sealing member 32 and spring element 20 within the fluid channel 14, when the stem 31 is actuated by an animal, the pivot point of upper end 33 of stem 31 about the bottom of spring element 20 tends not to be either predictable or consistent. Consequently, after actuation by an animal, stem 31, in certain circumstances, will

shift position in relation to spring element 20, thus not allowing spring element 20 to bias stem 31 back into the desired closed position.

[0072] With reference to FIG. 18, there is shown a fluid delivery valve assembly 200 that overcomes the above-discussed deficiency because, among other modifications, the arrangement of stem member 240, spring member 250, and sealing member 260 is different than that of their respective corresponding parts in fluid delivery valve assembly 1. This arrangement of stem member 240, spring member 250, and sealing member 260, discussed in detail below, provides for a predictable and consistent pivot point for stem member 240, thus facilitating a more consistent return to the closed position in the absence of actuation by an animal.

[0073] Thus, fluid delivery valve assembly 200 is different in structure and arrangement to that of fluid delivery valve assembly 1 in several respects. However, in accordance with the present invention, fluid delivery valve assembly 200 may be used in all embodiments discussed above with reference to fluid delivery valve assembly 1. Accordingly, in any embodiment described herein that describes the use of fluid delivery valve assembly 1 in conjunction with, by way of non-limiting example, fluid bag 60, animal isolation and caging rack system 600, and/or diet delivery system 96, fluid delivery valve assembly 200 may be used as well, in accordance with the invention.

[0074] With reference again to FIG. 18, there is shown fluid delivery valve assembly 200 having an upper member 210, and a base 220. Fluid delivery valve assembly 200 also includes sealing member 260, stem member 240, and spring member 250.

[0075] Upper member 210 is formed with generally conical piercing member 211 having sharp point 214 for piercing fluid bag 60 as described above. One or more fluid apertures 215 are defined in a portion of piercing member 210, to facilitate the flow of fluid 70

from bag 60 into a fluid channel 216 defined within the piercing member 210. Upper member 210 is also formed with connecting member 212, having gripping portion 213 encircling a portion thereof. In certain embodiments, stem member 240, base 220 and upper member 210 are formed of plastic, such as polypropylene. In certain embodiments, sealing member 260 is formed of silicone rubber, and spring member 250 is formed from stainless steel. Fluid delivery valve assembly 200 is, in certain embodiments, relatively low in cost, and disposable.

[0076] Base 220, being generally cylindrical in shape, includes top portion 221 and bottom portion 222, which are separated by flange member 226 which encircles base 220 and extends outwardly therefrom. Flange member 226 may be used to facilitate mounting or positioning of fluid delivery valve assembly 200 as is described above with regard to fluid delivery valve assembly 1. Top portion 221 may have an inner surface 223 with gripping portion 213 disposed thereon.

[0077] Upper member 210 is designed and dimensioned to be coupled to base 220 with connecting member 212 being inserted into base top portion 221. The coupling may be facilitated by the frictional interaction of gripping portion 213 of upper member 210 with gripping portion 224 of base 220.

[0078] Sealing member 260, stem member 240, and spring member 250 are disposed within base fluid channel 230. Stem member 240 has a top portion 241 that may be generally flat, such that flow aperture 265 of sealing member 260 may be advantageously sealed when a portion of bottom surface 262 of sealing member 260 is contacted by top surface 243 of stem member 240. Actuation portion 242 of stem member 240 extends through spring member 250 and through base fluid channel 230. Spring member 250 serves to bias stem member 240 against sealing member 260 to facilitate control of the flow of fluid, as described above with respect to fluid delivery valve assembly 1.

[0079] With reference to FIG. 19, spring member 250 is retained within base fluid channel 230 at its bottom end as fluid channel 230 has narrow portion 232, which serves to block spring member 250 from passing through and out of fluid channel 230. The top of spring member 250 abuts the lower surface 244 (see FIG. 20) of stem member 240. Spring member 250 serves to bias stem member 240 in a vertical orientation, thus forming a seal between top surface 243 and sealing member 260. This seal may be facilitated by the use of lower ridge 266 to concentrate the biasing force of spring member 250 to form a seal against stem member 240.

[0080] Turning to FIGS. 21 and 22, there is shown the operation of fluid delivery valve assembly 200 when stem member 240 is actuated by an animal. It should be noted that spring member 250 is not shown in FIGS. 21 and 22 for sake of clarity. During actuation of stem member 240 by an animal, however, as discussed above, spring member 250 provides a biasing force to bias stem member 240 toward a generally vertical position.

[0081] With reference to FIG. 21, stem member 240 is positioned generally vertically, with top surface 243 of stem member 240 advantageously abutting lower ridge 266 of sealing member 260 at sealing point 246. The use of lower ridge 266 in conjunction with top surface 240 advantageously serves to focus and concentrate the biasing force of spring member 250 to form a seal as discussed above.

[0082] Fluid delivery system 200 is shown having been punctured into fluid bag 60 such that fluid 70 may flow from fluid bag 60 into fluid aperture 215 of upper member 210, and in turn flow into fluid channel 216, through flow aperture 265 of sealing member 260, down to sealing point 246. At this point, with stem member 240 in the vertical (sealed) position, flow of the fluid is stopped.

[0083] In an embodiment of the invention, bag 60, once punctured by fluid delivery valve assembly 200, should have its outer wall positioned in the range along surface 235 of top portion 201 of base 220 such that it remains disposed in the portion delimited at its upper bounds by bag retention wall 217 and at its lower bounds by flange top surface 227. In an embodiment of the invention, flow aperture 215 and (in some embodiments) aperture portion 218 may be advantageously positioned about an edge of bag retention wall 217.

[0084] Turning now to FIG. 22, there is shown stem member 240 positioned as it would be while an animal actuates actuation portion 242 of stem member 240 in a direction B. Of course, one skilled in the art would recognize that the same result would be achieved so long as the stem member is actuated outwardly, out of its resting vertical position. Upon actuation in direction B, stem member 240 pivots about pivot point 236 such that top surface 243 of stem member 240 moves away from the lower ridge 266 of sealing member 260. This movement allows fluid 70 at flow aperture 265 of sealing member 260 to flow down through gap 237, into fluid channel 230, and out to the animal in the general direction A.

[0085] Base 220 may be formed with abutment wall 233 disposed in fluid channel 230 such that the maximum travel of stem member 240 is limited such that the flow of fluid 70 is advantageously limited to a desired value. Additionally, stem member 240, base 220, sealing member 250 and spring member 250 may be advantageously designed and dimensioned such that stem member 240 pivots at a consistent and predictable pivot point 236 and will thus not be subject to sticking or jamming in the open position after stem member 240 is released from actuation by the animal. Consequently, the wasting of fluid and the exposure of animals to hypothermia or other problems caused by excessive wetting of the cage and bedding material may be minimized.

[0086] Turning to FIG. 23, embodiments of the invention may be formed with base 220 of fluid delivery valve assembly 200 having extension portion 234. Extension portion 234 may serve, in certain application specific scenarios, to protect the actuation portion 242 of stem member 240 from being accidentally bumped by an animal, as only a portion of actuation portion 242 extends beyond extension portion 234. In an embodiment of the invention, the relative lengths L1 and L2 of extension portion 234 and actuation portion 242 may be adjusted based on the results desired, and the types of animals being fed, as well as other factors.

[0087] Referring to FIG. 24, in an embodiment of the current invention water delivery system 1 (or fluid delivery valve assembly 200) is sterilized and/or autoclaved and maintained in a sterilized state prior to use in a wrapper 47 or other suitable container so as to avoid infecting an animal in animal cage 90 (while, for sake of brevity, the embodiments of the invention discussed below make specific reference only to fluid delivery valve assembly 1, it is to be understood that fluid delivery valve assembly 200 may also be used in all instances as well). When a user determines that a clean water delivery system is needed in conjunction with a fluid bag 60, water delivery system 1 is removed from wrapper 47 in sterile conditions or utilizing non-contaminating methods and inserted into animal cage 90 in fluid bag receptacle 110 (while it is contemplated that all of fluid delivery valve assembly 1 would be contained within wrapper 47, only a portion of fluid delivery valve assembly 1 is illustrated in FIG. 24). Thereafter fluid bag 60 is placed in fluid bag receptacle 110 and is punctured by piercing member 11 such that fluid 70 (i.e., water) is released through fluid channel 14 to an animal in animal cage 90. This procedure insures that sterilized fluid 70 is delivered through an uncontaminated fluid channel and that fluid delivery valve assembly 1 is itself uncontaminated and pathogen free. Additionally, in an embodiment of the invention, fluid

delivery valve assembly 1 may be sold and stored in blister packs in groups of various quantities.

[0088] Referring to FIG. 25, in another embodiment of the invention the upper portion of fluid delivery valve assembly 1, including upper member 10 and piercing member 11, is covered with a disposable cap 45, that can be removed when a user wants to use water delivery system 1 to pierce fluid bag 60 and place it in fluid bag receptacle 110 for delivery of a fluid to an animal in animal cage 90. Disposable cap 45 can be made from any suitable material and may be clear, color-coded to indicate the type of fluid in fluid bag 60, clear or opaque.

Disposable cap 45 is easily removed from fluid delivery valve assembly 1. While cap 45 would not provide for a sterilized fluid delivery valve assembly 1, it would provide a labeling function, as well as, in an embodiment, provide protection from inadvertent stabbing of a user.

[0089] An embodiment of the present invention provides a system and method for fluid delivery to one or more animal cages. The system provided has at least two methods of use, one which includes providing sealed sanitized bags of fluid for use in an animal cage or caging system. The provider provides the pre-packaged and uncontaminated fluid (e.g., water, or fluid with nutrients etc., as needed by an animal) for use preferably by delivering sanitized, fluid-filled, bags to a site designated by a user. Alternatively, the provider may locate a sealing apparatus, material for making the fluid bags and fluid supply at a location designated by the user. Thereafter, the provider will assemble, fill and seal the appropriate number of fluid bags for a user at the designated location. In a second method the provider provides a sealing apparatus and the material for making the fluid bags to a user. In this second method the provider may also supply any appropriate fluid to the user at a location designated by the user. The user thereafter assembles, fills and seals the fluid bags for use in the fluid delivery system of the invention as appropriate.

[0090] A fluid bag (or pouch) filling and sealing method and system 300, in accordance with an embodiment of the invention, is illustrated in FIG. 26. Bag material (or film) 310, which may be formed of any suitable material as described above, is stored in bulk form, such as, for example, in roll form. As the process continues, bag material 310 is moved over bag forming portion 330 such that the generally flat shape of bag material 310 is formed into a tube. As the process continues, a vertical seal device 340 forms a vertical seal in bag material 310, thus completing the formation of a tube.

[0091] Contents supply portion 320 serves to add ingredients, via, for example, gravity feed, into the tube of bag material 310. Contents supply portion 320 may include liquid and powder storage containers, and various pumps and other supply means, such that, for example, fluid (or water) 70, either with or without any additives as discussed above, may be added and metered out in appropriate quantities as is known in the art. Additionally, contents supply portion 320 may include heating and/or sterilizing equipment such that the contents supplied from contents supply portion 320 are in a generally sterilized condition.

[0092] Next, horizontal seal device 350 forms a horizontal seal, either thermally, by adhesives, or by some other art recognized method as would be known to one skilled in the art. The horizontal seal serves to isolate the contents of the tube into separate portions. Next, the bag cutting device cuts the bag material at the horizontal seal to form individual fluid bags 60 containing fluid 70.

[0093] Of course, in accordance with the spirit of the invention, the exact steps taken to form the fluid bags 60 may be varied as a matter of application specific design choice. In some embodiments of the invention, steps may be added, left out, or performed in a different order. Additionally, the contents and bag material 310 of fluid bags 60 may be sterilized either before or after the completed bags are formed, or not at all.

[0094] In an embodiment of the invention, and with reference to FIGS. 27-29, the fluid 70 is heated to approximately 180° F, and the fluid bags are stacked in storage containers 370 with the result that the fluid 70, fluid bags 60 and storage containers all become sterilized to a satisfactory degree. In an embodiment of the invention, a cage body 98 may be used as such a storage container. Additional parts of this process may also be automated, as is shown by the use of robotic arm 380 in stacking containers.

[0095] Storage containers (or totes) 370 (or cage bodies 98) may also be supplied with fluid bags 60 at a workstation 382, before placement in a isolation and caging rack system 600. Additionally, storage containers 370 (or cage bodies 98) may be passed through various other sterilizing devices.

[0096] As described above, the provider may provide a bag filling and sealing apparatus and the material for making the fluid bags to a user. The user thereafter assembles, fills and seals the fluid bags for use in the fluid delivery system in accordance with certain embodiments.

[0097] In such instances, the filling and sealing apparatus can be installed on site at, for example, research laboratories, pharmaceutical companies, government agencies, universities, contract research companies, breeders and chemical companies, among others. Typically, these types of facilities are frequently Association for Assessment and Accreditation of Laboratory Animal Care International (AALAC) inspected and require approval with respect to Good Laboratory Practice (GLP) U.S. Department of Health and Human Services Food and Drug administration (FDA) requirements to run such a facility. To meet these strict certification requirements, these facilities generally have a central wash room complex where equipment such as cages and racks and other accessories are routinely sent to be cleaned washed and sanitized using washing machines, detergents, and the like. Typically, these areas

are organized and fed from building flow patterns referred to as the dirty side of the wash area and clean side of the wash area. This is done to prevent the transfer of dirty particles into clean corridors wherein the animal rooms are re-supplied with clean equipment and animals. In accordance with these flow patterns, people at the facilities also follow the flow patterns, and may also be required to wear protective clothing such as gowning and disposable shoe covers. The flow patterns also pertain to the movement of equipment. Equipment being brought to the laboratory rooms must get there by way of the clean side of the rack washer in the wash room.

[0098] The dirty side of the wash room typically contains rack washers, cage tunnel washers, autoclaves, disposal cans for dirty bedding and the like. These machines are typically set in concrete pits and are plumbed and wired as permanent installations in the facility building. Most of the equipment is accessed through doors that allow loading of racks, cages and equipment that are placed into these washing machines. These machines are typically positioned flush with a washroom divider wall. Equipment is placed in the washing machine at the dirty side, passes through an opening in the wall, and exits on the clean side of the washroom. After the equipment is loaded, it is typically washed with hot water and detergents for approximately fifteen to twenty minutes. On the clean side, after the wash cycle is complete, staff will then open the doors and remove the washed equipment into the clean staging area. The floors in these clean areas are typically formed of tile, epoxy, and/or epoxy stone mix, to create a waterproof area, with floor drains. Racks (like cars in a car wash) come out dripping wet, and the drains facilitate drainage of dripping water. Other activities typically performed on the clean side of the wash room include the filling of bottles with water and the charging of cage racks with water (i.e., purging the rack automatic watering system). Accordingly, because the charging of racks is typically performed on the clean side of the wash room, the clean side typically contains access to the main house feed of water, as well as a

water treatment and/or filtration system. Such a system may consist of systems for the chlorination, acid treatment, and/or micron filtration of the water. Also typically included in such a system is a pressure reduction station to allow connection of the treated water to racks configured for automatic watering, to fill them and purge the racks from old water latent in the systems.

[0099] As stated above, the bag filling and forming apparatus can be advantageously located at the clean side of the wash room. In certain embodiments, the bag filling and forming apparatus requires about sixteen square feet of floor space, although alternatively, the apparatus may be configured to require more or less floor space. In certain embodiments, the bag filling and forming apparatus can include industrial grade casters and can be rolled into place. The bag filling and forming apparatus can comprise built-in floor jacks that allow leveling and semi-permanent location, once placed. In certain embodiments, the bag forming and filling apparatus is pre-wired and fitted to accept a 110/220 VAC , 20 amp, 50/60 Hz supply dedicated power line near the machine. Of course, other power supplies could be used as is known to those skilled in the art, as instructed by this disclosure.

[00100] With reference to FIG. 30, in certain embodiments, a 1 1/2 inch cold water line 420 downstream of the existing in-house treatment system is used to supply water to the bag filling and forming apparatus 450. Of course, other water line sizes could be used as is known to those skilled in the art, as instructed by this disclosure. As described above, in certain embodiments, the bag (or pouch) material is provided in rolls 410. In such embodiments, a mobile roll lifting device 430 may be provided to the clean side of the wash room so that rolls of bag material 410 may be easily maneuvered from, for example, a pallet, to the bag filling and forming apparatus 450. In certain embodiments of the system, an indexing or other type motor driven conveyor 460 can also be located on the clean side of the wash room to facilitate

transport of the filled water bags 440 away from the filling and forming apparatus. Box-shaped totes 470, preferably formed of translucent plastic, can also be provided at the clean side of the wash room. In certain embodiments, the totes 470 can be rigid such that they may be stacked when full, and nested when empty for easy storage. In certain embodiments, a mobile tote conveyor platform 465 can be used to position an open tote 470 at the end of motorized conveyor 460 until the tote 470 is filled with full water bags 440. The mobile tote conveyor platform 465 can then be moved to a tote cart 480. Tote cart 480 can be provided to facilitate the transport of the totes 470 filled with water bags 440 to a laboratory or other area. Generally, in certain embodiments, the water bags 440 are filled and formed in the clean side of the washroom, and then the totes 470 are filled and stored with the full water bags 440. The totes 470 can then be transported on the tote cart 480 to rooms and/or hallways where animal cages need service and a re-supply of water. Disposable valves (e.g., valves formed with plastic components) can then be removed from sanitized packaging, and inserted into apertures in diet delivery systems or wire bar lid inserts, and then, in turn, the water bags (or pouches), can be positioned such that the valves pierce the water bags and water may flow from the bags, through the valves, and be accessed by animals in cages. In alternate embodiments, the valves used need not be disposable or plastic, but could be formed of stainless steel or other suitable materials as is known to those skilled in the art.

[00101] The used (near empty) pouches are removed from the cages, are placed in containers, such as, for example, empty totes, and transported to the dirty side of the washroom area. In certain embodiments, a compactor/bagging machine 490 can be supplied to the dirty side of the washroom. The compactor can be used to compress used pouches and valves into a compact bundle, or disposable bag, for easy disposal.

[00102] With reference to FIG. 31, there is shown a schematic of a typical flow path at a laboratory facility 500. Laboratory research rooms 510 are located between dirty corridor 520 and clean corridor 530. Laboratory exits 512 connect the laboratory research rooms 510 with the dirty corridor 520, while laboratory entrances 514 connect the laboratory research rooms 510 to the clean corridor 530. The central washroom 540 is also positioned between the dirty corridor 520 and the clean corridor 530. Washroom entrance 542 leads from dirty corridor 520 to the dirty side 546 of the washroom 540. As described above, a compactor/bagging machine 490 to facilitate disposal of water bags 440 and valves can be placed at the dirty side 546 of washroom 540. The clean side 548 of the washroom 440 is connected to clean corridor 530 via washroom exit 544. As described above, in certain embodiments, bag filling and forming apparatus 450 is located at the clean side 548 of washroom 540. As described above, in a typical flow path, water bags are produced by the water bag filling and forming apparatus 450 at the clean side 548 of washroom 540. The water bags are transported out exit 544 into clean corridor 530, and then through one of the laboratory entrances 514 into one of the laboratory research rooms 541 where the water bags are placed into cage level barrier-type cages. The used water bags are removed from the cages, placed into empty totes, and transported out one of the laboratory exits 512 into dirty corridor 520, and then through washroom entrance 542 into the dirty side 546 of washroom 540, where, in certain embodiments, the used water bags and valves are compacted in a compactor/gagging apparatus 490 for easy removal. In certain embodiments, the compacted water bags and valves can be washed prior to removal.

[00103] With reference to FIG. 32, there is shown a schematic of another typical flow path at a laboratory facility 700. Laboratory research rooms 710 are located next to corridor 725. Laboratory combined entrance/exits 713 connect the laboratory research rooms 710 with

the one way corridor 725. Washroom entrance 742 leads from corridor 725 to the dirty side 746 of the washroom 740. The clean side 748 of the washroom 740 is connected to corridor 725 via washroom exit 744. As described above, in certain embodiments, bag filling and forming apparatus 450 is located at the clean side 748 of washroom 740. As also described above, in a typical flow path, water bags are produced by the water bag filling and forming apparatus 450 at the clean side 748 of washroom 740. The water bags are transported out exit 744 into one way corridor 725, and then through one of the laboratory entrance/exits 713 into one of the laboratory research rooms 741 where the water bags are placed into cage level barrier-type cages. The used water bags are removed from the cages, placed into empty totes, and transported out one of the laboratory entrance/exits 713 into corridor 725, and then through washroom entrance 742 into the dirty side 746 of washroom 740, where, in certain embodiments, the used water bags are compacted for easy removal.

[00104] With reference to FIG. 33, there is illustrated an exemplary method 800 of providing water bags in accordance with certain embodiments. In this method, a rack and cage system having a plurality of cage level barrier-type cages is provided at a laboratory research room for performing an animal study. Step 810. Next, bag material (or film), for the water bags (or pouches) is provided to the laboratory facility site. Step 820. Next, a water bag filling and forming apparatus is provided to the clean side of the washroom at the laboratory facility. Step 830. Next, disposable valves are provided for use with the water bags. Step 840. In this embodiment, for sake of clarity, the steps are depicted being performed one at a time, in a specific order. The steps need not be performed in the depicted order shown, however, and the various steps may be performed in other orders, and/or one or more of the steps may be performed simultaneously. In addition, in certain embodiments, one or more of the steps may

be omitted, and/or one or more of the steps may be performed more than once, and/or additional steps may also be performed.

[00105] Another method 900 of providing sealed water bags for use in cage level barrier-type cages for animal studies is depicted in FIG. 34. In certain embodiments, a rack and cage system is provided for placement in a laboratory research room. Step 910. Bag material (film) is provided. Step 920. Next, in certain embodiments, a roll lift device is provided so that rolls of bag material may be easily maneuvered from pallets to the bag filling and forming apparatus. Step 930. Next, a water bag filling and forming apparatus is provided at the clean side of the washroom. Step 940. Next, a conveyor system is provided for the handling of the water bags after they are produced by the water bag filling and forming apparatus. Step 950. Next, totes for storing and transporting the filled water bags can be provided. Step 960. A tote cart for transporting several totes can then be provided. Step 970. Next, disposable fluid delivery valves can be supplied for insertion into the diet delivery system or module. Each of the filled water bags is then positioned in a diet delivery module such that a valve pierces the bag and water may flow out of the bag, through the valve, and be accessed by animals. Step 980. Used water bags and valves are transported from the clean side of the facility to the dirty side of the facility. Next, a compactor/bagging apparatus (disposal device) is provided for compacting the used water bags and valves after use. Step 990. In this embodiment, for sake of clarity, the steps are depicted being performed one at a time, in a specific order. The steps need not be performed in the depicted order shown, however, and the various steps may be performed in other orders, and/or one or more of the steps may be performed simultaneously. In addition, in certain embodiments, one or more of the steps may be omitted, and/or one or more of the steps may be performed more than once, and/or additional steps may also be performed.

[00106] Accordingly, by way of providing a bag forming apparatus at a clean side of a laboratory washroom at the laboratory facility site, wherein the bag forming apparatus is capable of providing sealed bags of water for use in the cage level barrier-type cages, users at a laboratory facility are freed from the significant investment in time and expense necessitated by the use of water bottles. In addition, the laboratory facility is also freed from the expense and dangers related to the use of automatic watering systems.

[00107] Because the bag forming apparatus is provided at the clean side of the laboratory washroom, the laboratory facility may take advantage of the features of the washroom, such as the presence of a main water feed, and dedicated power circuits. In addition, by providing water bags at the clean side of the laboratory facility washroom, personnel at the laboratory facility may make use of their pre-existing clean and dirty flow paths, thus allowing for harmonious integration of the water bag and fluid delivery valve system into the existing laboratory facility environment.

[00108] Thus, while there have been shown and described and pointed out fundamental novel features of the invention as applied to exemplary embodiments thereof, it would be understood that various omissions and substitutions and changes in the form and details of the disclosed invention may be made by those skilled in the art without departing from the spirit of the invention. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

[00109] It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention that, as a matter of language, might be said to fall there between.